UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,348	07/29/2003	Navin Vaya	1296-016	9293

47888 7590 10/05/2006

HEDMAN & COSTIGAN P.C.
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER	
MERCIER, MELISSA S	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,348	VAYA ET AL.	
	Examiner	Art Unit	
	Melissa S. Mercier	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-29 and 31-59, drawn to a modified release dosage form, classified in class 424, subclass 469.

II. Claims 30 and 60, drawn to processes for the preparation of a modified release dosage form, classified in class 424, subclass 489.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case modified release dosage forms are well known in the art and can be prepared by using pH dependent coating materials as to allow the release of the active ingredients at different parts of the digestive tract.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species:

Types of Hydrophobic Release Agents:

a. ammonio methacrylate copolymers type A and B

b. methacrylic acid copolymer type A,B, and C

c. polyacrylate dispersion 30

d. polyvinyl acetate dispersion,

e. ethylcellulose,

f. cellulose acetate

g. cellulose propionate (lower, medium, or higher molecular weight)

h. cellulose acetate propionate

i. cellulose acetate butyrate

j. cellulose acetate phthalate

k. cellulose triacetate

l. poly(methyl methacrylate)

m. poly(ethyl methacrylate)

n. poly(butyl methacrylate),

o. poly(isobutyl methacrylate)

p. poly (hexyl methacrylate)

q. poly(isodecyl methacrylate)

r. poly (lauryl methacrylate)

s. poly(phenyl methacrylate)

t. poly (methyl acrylate)

u. poly (isopropyl acrylate)

v. poly (isobutyl actylate

w. poly (octadecyl acrylate)

x. waxes

y. fatty alcohols

z. fatty acid esters

aa. hydrogenated castor oil

Types of Hydrophobic Release Agents employed for coating the micro-matrix particles:

a. ammonio methacrylate copolymers type A and B

b. methacrylic acid copolymer type A, B, and C

c. polyacrylate dispersion 30

d. polyvinyl acetate dispersion,

e. ethylcellulose,

f. cellulose acetate

g. cellulose propionate (lower, medium, or higher molecular weight)

h. cellulose acetate propionate

i. cellulose acetate butyrate

j. cellulose acetate phthalate

k. cellulose triacetate

l. poly(methyl methacrylate)

m. poly(ethyl methacrylate

n. poly(butyl methacrylate),

o. poly(isobutyl methacrylate)

p. poly (hexyl methacrylate)

q. poly(isodecyl methacrylate)

r. poly (lauryl methacrylate)

s. poly(phenyl methacrylate)

t. poly (methyl acrylate)

u. poly (isopropyl acrylate)

v. poly (isobutyl actylate

w. poly (octadecyl acrylate)

x. waxes

y. fatty alcohols

z. fatty acid esters

aa. hydrogenated castor oil

Generic Type of High Solubility Active Ingredient:

a. anti-diabetic agents

b. anti-histamines

c. anti-depressants

d. anti-viral agents

e. anesthetics

f. antacids

g. anti-arthithriics

h. antibiotics

i. anti- psychotics

j. anti-spasmodics,

k. anxiolytic agents

l. appetite suppressants

m. cough suppressants

n. cardiovascular agents

o. emollients

p.gastro-intestinal agents

q. growth regulators

r. respiratory stimulants

s. vitamins

t. angiotensin converting enzyme inhibitors

u. anti-asthmatics

v. anti-cholesterolemnics

w. anticonvulsants

x. anti-diarrhea prepartations

y. anti-infectives

z. anti inflammatory agents

aa. anti nauseants

bb. anti stroke agents

cc. anti tumor drugs

dd. anti tussives

ee. anti uricemic drugns

ff. amino acid preparations

gg. antiemetics

hh. antiobesity drugs

ii. antiparasitic

jj. antipyretics

kk. celebral dilators

ll. chelating agents

mm. cholecystokinin antogonsit

nn. cognition activators

oo. deodorants

pp. dermatological agents

qq. diuretics

rr. erythropoietic drugs

ss. fertility agents

tt. synthetic hormones

uu. laxatives

vv. mineral supplements

ww. neuroleptics

xx. neuromuscular agents

yy. peripheral vaso dilators

zz. prostaglandins

aaa. vaginal prepartations

bbb. vaso contrictors

ccc. vertigo agents

ddd. biguandines

eee. sulphoylurease

fff. meglitinides

ggg. PPAR gama agonist alpha glucosidase inhibitors

Applicant is further required to elect a specific active ingredient for the generic group of active ingredients.

Specific Type of High Solubility Active Ingredients:

a. metformin HCl

b. phenformin

c. buformin

d. captopril

e. rantidine HCl

f. KCl

g. Clindamycin

h. Hydroxyurea

i.Erythromycin

j. Lactobionate

k. Vancomycin HCl

l. Balsalazide disodium

m. Aminocaproic acid

n. Lisinopril

o. Tramadol

p. Acetaminophen

q. Ciprofloxacin

s. Esters of ampicillin

t. Sodium valproate

u. Niacin

v. Diltiazem

w. Venlafaxine

x. Isosorbide 5-imononitrate

y. Isoborbide dinitrate

z. Pentoxyphylline

aa. Propranolol

bb. Quetiapine

Type of High Solubility Potent Active Ingredient:

a. antidiabetic agents

b. anti-histamines

c. anti-depressants

d. anti-viral agents

e. anesthetics

f. antacids

g. anti-arthithriics

h. antibiotics

i. anti- psychotics

j. anti-spasmodics,

k. anxiolytic agents

l. appetite suppressants

m. cough suppressants

n. cardiovascular agents

o. emollients

p.gastro-intestinal agents

q. growth regulators

r. respiratory stimulants

s. vitamins

t. angiotensin converting enzyme inhibitors

u. anti-asthmatics

v. anti-cholesterolemnics

w. anticonvulsants

x. anti-diarrhea prepartations

y. anti-infectives

z. anti inflammatory agents

aa. anti nauseants

bb. anti stroke agents

cc. anti tumor drugs

dd. anti tussives

ee. anti uricemic drugs

ff. amino acid preparations

gg. antiemetics

hh. antiobesity drugs

ii. antiparasitic

jj. antipyretics

kk. celebral dilators

ll. chelating agents

mm. cholecystokinin antogonsit

nn. cognition activators

oo. deodorants

pp. dermatological agents

qq. diuretics

rr. erythropoietic drugs

ss. fertility agents

tt. synthetic hormones

uu. laxatives

vv. mineral supplements

ww. neuroleptics

xx. neuromuscular agents

yy. peripheral vaso dilators

zz. prostaglandins

aaa. vaginal prepartations

bbb. vaso contrictors

ccc. vertigo agents

ddd. biguandines

eee. sulphoylurease

fff. meglitinides

ggg. PPAR gama agonist alpha glucosidase inhibitors

Applicant is further required to elect a specific potent active ingredient for the generic group of active ingredients.

Specific Type of High Solubility Potent Active Ingredients:

a. benzotropine mesylate

bdistigmine bromide

c. fluprenthixol dihydrochloride

d. formotexol fumerate

e. glycopynolete

f. granisetron hydrochloride

g. bisoprolol fumerate

h. atropine sulphate

i. azatadine maleate

j. carteolol HCl

k. bromphenaramine maleate

l. nicotine

m. oxybutamine chloride

n. perinodopril erbumine

o. pilocorpine

p. poldine methyl sulfate

q. zalcitane

The species are independent or distinct because they can be used to make patentably distinct dosage formulations having different and distinct functions.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1 and 31 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa S. Mercier whose telephone number is (571) 272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MSMercier

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600